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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,799	01/04/2002	J. Bruce Pitner	P-5504	9195

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EXAMINER

TELLER, ROY R

ART UNIT PAPER NUMBER

1654

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/039,799	<b>Applicant(s)</b> PITNER ET AL.	
	<b>Examiner</b> Roy Teller	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 14-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>0404</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This office action is in response to the restriction/election, received 1/26/04, in which applicant elected group I, claims 1-13, without traverse.

Claims 14-28 are withdrawn as being drawn to a non-elected invention.

Claims 1-13 are pending.

### ***Information Disclosure Statement***

The information disclosure statement filed 3/31/03 is acknowledged. A signed copy is attached hereto.

### ***Claim Objections***

Claim 2 is objected to because of the following informalities: A claim cannot depend upon itself. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

With respect to the elected invention, claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mutated glucose binding protein which includes one amino acid substitution selected from the group consisting of a cysteine at position 74, a cysteine at position 149, or a cysteine at position 213 does not reasonably provide enablement for a mutated glucose binding protein which includes one amino acid substitution selected from the group consisting of a cysteine at position 11, a cysteine at position 14, a cysteine at position 19, a cysteine at position 43, a cysteine at position 107, a cysteine at position 110, a cysteine at position 112, a cysteine at position 113, a cysteine at position 137, a cysteine at position 216, a cysteine at position 238, a cysteine at position 287, a cysteine at position 292, and mutated glucose binding protein which includes at least two amino acid substitutions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

With respect to the elected invention, Applicants have reasonably demonstrated that for a mutated glucose binding protein which includes one amino acid substitution selected from the group consisting of a cysteine at position 74, a cysteine at position 149, or a cysteine at position 213 results in signal-enhanced glucose detection as evidenced by figure 1 and figure 8 of the instant application. However, the claims broadly encompass a group of amino acid substitutions for a mutated glucose binding protein which are clearly beyond the scope of the instant disclosure.

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Accordingly, with respect to the elected invention, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success, other than using a mutated glucose binding protein which includes one amino acid substitution selected from the group consisting of a cysteine at position 74, a cysteine at position 149 , or a cysteine at position 213 results in signal-enhanced glucose detection as evidenced by figure 1 and figure 8 of the instant application.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakawicz (USPN 6,197,534) or by Hellinga (USPN 6,277,627).

The instant invention is drawn to a biosensor comprising at least one mutated binding protein and at least one thiol group and at least one sensor surface which provides a detectable signal resulting from a change in refractive index when the mutated binding protein binds to analyte.

Each of the cited references teach a sensor comprising a modified glucose binding protein (see '534 patent 30, 32, 33, 34, 35, 37 38, and 40, columns 15 and 16 and '627 patent, claim 1,

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column 11). Further, Lakawicz et al. expressly teach the protein is modified by substituting at least one cysteine residue (see claims 37 and 38, columns 15 and 16).

Accordingly, each of the cited references is deemed to anticipate the above claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lakawicz (USPN 6,197,534) or by Hellinga (USPN 6,277,627).

The references are relied upon for the reasons set forth above. The adjustment of particular conventional working conditions (e.g., at least one thiol group attached to at least one mutated binding protein ) is deemed clearly to be a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, based upon the beneficial teachings provided by one or more of the cited references with respect to a biosensor comprising at least one mutated binding protein selected from glucose binding protein.

### ***Conclusion***

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All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (571) 272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571)272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRISTOPHER R. TATE  
PRIMARY EXAMINER